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| 10/633,443      | 08/04/2003  | Melvin E. Knisley    | AMC3779             | 4689             |

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EXAMINER

ISABELLA, DAVID J

ART UNIT PAPER NUMBER

3738

DATE MAILED: 03/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/633,443

Applicant(s)

KNISLEY, MELVIN E.

Examiner

DAVID J ISABELLA

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 04 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 6, 10 is/are rejected.
- 7) ☒ Claim(s) 7-9 and 11 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 8/4/03.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

***Status of the Claims***

Claims 1-11 were filed on 8/4/03. No preliminary amendment was filed and a PTO1449 was filed concurrently with the claims.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

**Claims 6 and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.**

Claim 6 is dependent on claim 1 which is directed to a prosthetic device. The body of claim 6 introduces an injector element which fails to further define the device of claim 1. It is not clear if applicant wishes to positively claim the combination of a prosthetic device and an injector or if the claim is to a prosthetic device capable of being used in combination with an injector. If applicant wishes to positively claim the combination then the preamble of claim 1 should be changed to reflect such change (eg system, kit, assembly, etc.).

Claim 11, see rejection to claim 1 supra.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**Claims 1,3-5 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nakahira (4429268) in view of Becker (4643733), Chu (5823852), Eaton (6520989) and Austad (4157085).**

Nakahira discloses that nitrile rubber may be used as medical prosthetic material including in the fabrication of artificial breast (see column 5, lines 10-17). Nakahira does not disclose specifics regarding the prosthesis itself. Becker and Chu show two forms of artificial breasts. One form is for implantation into the patient (Becker) and the other form is for external application on the wearer (Chu). Both Becker and Chu show a breast device having selective inflation including a housing having a back wall having a peripheral edge, a front wall being attached to and extending along a length of the peripheral edge such that an inner space is defined between the front and back walls. The front wall having a convex shape such that said front wall extends outwardly away from said back wall, the housing having an opening therein. Both Becker and Chu show a plug being removably extendable into opening; and wherein a fluid may be selectively added into or removed from said housing until said housing has a desired size. Neither Becker or Chu disclose the features of the back and front walls comprising a latex material having a thickness generally between .08 mm and 2.0 mm.

Eaton (external breast prosthesis) and Austad (implantable breast prosthesis) teach a range of wall thickness including values falling within the range as claimed by applicant.

One with ordinary skill in the art would look to what is known in the prior art including features directed to the prosthesis physical characteristics including dimensions such as wall thickness, implant size (eg height, width, length, etc.) and filling valves or ports. Nakahira establishes that artificial breast device may be made from nitrile rubber. The secondary references teach the various physical characteristics that are known in the art including wall thickness, implant size (eg height, width, length, etc.) and filling valves or ports. Applicant has put forth a claim that utilizes a collection of features known in the art. These features include the use of latex to keep the cost of the device low, one way valve positioned in an aperture to prevent leakages from the device, and cloth encasement to offer comfort from the latex. Each feature as claimed has been used in the art prior to applicant's invention for the same reasons as put forth by the applicant. It is the examiner's contention that the combination of the latex, aperture/valve and encasement would have been obvious to one with ordinary skill in the art as known physical characteristics selected by the designer based upon routine experimentations to meet the particular design criteria for the artificial breast device. To make the device with a back wall having a peripheral edge, a front wall being attached to and extending along a length of said peripheral edge such that an inner space is defined between said front and back walls is fairly standard in the art. The front wall having a convex shape such that said front wall extends outwardly away from said back wall, too, is fairly standard in the art. The device having a wall forming a housing with an opening therein and wherein a fluid may be selectively added into or removed from said housing until said housing has a desired size is known to be well

established in the art. A plug being removably extendable into opening to fill the housing of an external or internal device is clearly taught by Becker and Chu. said back wall and said front wall having a thickness generally between .08 mm and 2.0 mm is clearly taught by either of Austad or Eaton. Finally the use of nitrile latex is disclosed by Nakahira.

Claim 3, see table #3 of Nakahira.

Claim 4, see Nakahira.

Claim 5, since the devices of the prior art are prosthetic breast devices and function as such, it is inherent that the particular dimensions as claimed would fall within the dimensions of the devices of any of Becker, Chu, Eaton and Austad.

Claim 10, the encasement as claimed is readable on the brassiere of Chu which has at least one opening for receipt of the breast device.

**Claims 2,6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nakahira (4429268) in view of Becker (4643733), Chu (5823852), Eaton (6520989) and Austad (4157085) as applied to claim 1 above, and further in view of Hamas (5496370).**

Hamas shows a breast device including a housing having openings formed on the front and/or back portion of the device. While the valve locations of Chu and Becker are not specifically set forth, Hamas teaches that the placement of the valve may be on the front and/or back portion of the device. If not inherent in either of Chu or Becker, to place the valve at locations including the front and/or back portion of the device would

have been obvious to one with ordinary skill in the art depending on the selected design parameters in the manufacturing process.

Claim 6, each of Becker and Chu teach the use of an one way valve fluidly coupled to the aperture and positioned within the inner space of the housing for preventing fluid from exiting the housing. Location of the valve maybe centrally located as shown in figure 3 of Hamas. Since claim 6 depends from claim 1 and the preamble of the claim is directed to the prosthetic device, the examiner has interpreted the claim as being capable of being used with an injector.

***Allowable Subject Matter***

**Claims 7-9 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.**

**Claim 11 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action.**

***Information Disclosure Statement***

The information disclosure statement filed 8/4/03 includes entry to Strain. There is inadequate information concerning the document number pertaining to Strain.

Accordingly, Strain has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609 ¶ C(1).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DAVID J ISABELLA whose telephone number is 703-308-3060. The examiner can normally be reached on MONDAY-FRIDAY.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, CORRINE MCDERMOTT can be reached on 703-308-2111. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



DAVID J. ISABELLA  
Primary Examiner  
Art Unit 3738

DJI  
MARCH 4, 2004